IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No: 10/605,125

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Applicant(s): Walsh et al.

Confirmation No: 2124

Group Art Unit: 3686

Examiner: John A. Pauls

Title: COMPUTER BASED CLINICAL LABORATORY ORDERING AND REPORTING SYSTEM WITH EMBEDDED CONSULTATION FUNCTION

Attorney Docket No: 36497-3

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APPEAL BRIEF

This brief is submitted in support of the Notice of Appeal of the Final Rejection filed December18, 2009.

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I. Real Party in Interest

Inventors Bruce Friedman, M.D., and Francis Michael Walsh, M.D., are the real parties in interest in this matter.

II. Related Appeals and Interferences

There are no other known appeals or interferences which will directly affect or be directly affected by or have bearing on the Board's decision in the pending appeal.

III. Status of the Claims

Claims 1-28 are pending in the application. Each claim stands finally rejected.

The rejection of Claims 1-28 is being appealed.

IV. Status of Amendments

No amendments were filed following the Final Rejection.

V. Summary of Claimed Subject Matter

Claims 1, 14, 16, and 22 are the independent claims in this case. The Claims are best understood with reference to Figures 1 and 2A-2B, and with reference to the following citations to Appellants' specification.

Independent Claim 1

A system, 14, (Fig. 1) for providing clinical laboratory test ordering and results reporting with an embedded consultation service includes an order entry subsystem, 10, for submitting orders for at least one diagnostic test (¶38; ln 1-2), and a laboratory, 24, for receiving orders and for managing patients to fill the orders (¶38; ln.4-8). A data storage subsystem, 18, receives and retains test results from laboratory 24 (¶43; ln.1-3). A triage subsystem, 20, compares test results downloaded from data storage subsystem 18 with a predetermined reference range specific to such results, with triage subsystem 20 setting an abnormal results flag in the event that the test results are outside of the reference range. (¶38; ln.8-11, and ¶43; ln.3-10) A reporting-consulting

subsystem, 22, receives the results of the comparison from triage subsystem 20 (¶38; ln.8-18), with reporting-consulting subsystem 22 transmitting the processed test results, including at least the results of the comparison, to the person requesting the diagnostic test (¶38; ln.11-15) with reporting-consulting subsystem 22 further transmitting results bearing an abnormal results flag to an embedded consultant (¶38; ln.8-11), with reporting-consulting subsystem 22 providing at least one template for selection by a consultant to generate a consultative report concerning the test results. (¶38; ln.15-17).

Independent Claim 14

A system, 14, (Fig. 1) for facilitating the provision of clinical laboratory services includes an Internet based order entry subsystem, 10, accessible by clinicians, for submitting orders for at least one diagnostic test (¶38; ln 1-2), and a laboratory, 24, for receiving orders and for managing patients to fill the orders (¶38; ln.4-8). A data storage subsystem, 18, receives and retains contemporary and archival test results from laboratory 24 (¶43; ln.1-3, ¶46; ln.7-11).

A triage subsystem, 20, compares test results downloaded from data storage subsystem 18 with a predetermined reference range specific to such results, with triage subsystem 20 setting an abnormal results flag in the event that the test results are outside of the reference range. (¶38; ln.8-11, and ¶43; ln.3-10) A reporting-consulting subsystem, 22, receives the results of the comparison from triage subsystem 20 (¶38; ln.8-18), with reporting-consulting subsystem 22 transmitting the processed test results, including at least the results of the comparison, to the person requesting the diagnostic test (¶38; ln.11-15) with reporting-consulting subsystem 22 further transmitting results bearing an abnormal results flag to an embedded consultant (¶38; ln.8-11), with reporting-consulting subsystem 22 providing at least one template for selection by

an embedded consulting physician using a networked terminal, with the consultant generating a consultative report based upon the test results. (¶38; ln.15-17).

Independent Claim 16

A method for providing clinical laboratory services, including:

submitting an order to a laboratory for a diagnostic test by means of a networked terminal device, 204 (¶40; ln.1-10);

managing a patient to fill said test order, thereby generating test results, 208 (¶41; ln.4-13);

loading test results into a data storage subsystem, 212 (¶43; ln.1-2);

comparing test results contained within the data storage subsystem with predetermined reference range values, 216 (¶43; ln.3-7) , and thereafter causing the test results to be transmitted directly to the test requestor, using a networked terminal device, in the event that the test results are within said reference range, 228 (¶44; ln.1-8), but causing the test results to be transmitted by a networked terminal device to a consulting physician via a consultative reporting-consulting subsystem in the event that the test results are outside said reference range, 240 (¶45; ln.1-5);

receiving test results lying outside of the reference range in a reporting-consulting subsystem, and using said reporting-consulting subsystem to provide at least one selectable report template, 244 (¶46; ln.1-4);

using the report template and said consulting physician to generate a consultative report based at least in part upon the test results, 256 (¶47; ln.1-10); and

communicating the consultative report, bearing an electronic signature, to the test requester by means of a networked terminal device, 276 (¶53; ln.3-4).

Independent Claim 22

A system, 14, (Fig. 1) for providing of clinical laboratory services includes an Internet based order entry subsystem, 10, accessible by clinicians, for submitting orders for at least one diagnostic test (¶38; ln 1-2), and a data storage subsystem, 18, receiving and retaining test results from a laboratory, 24 (¶43; ln.1-3, ¶46; ln.7-11). A triage subsystem, 20, compares test results downloaded from data storage subsystem 18 with predetermined range values specific to such results, with triage subsystem 20 setting an abnormal results flag in the event that the test results are outside of the reference range. (¶38; ln.8-11, and ¶43; ln.3-10) A reporting-consulting subsystem, 22, receives the results of the comparison from triage subsystem 20 (¶38; ln.8-18), with reporting-consulting subsystem 22 transmitting the processed test results, including at least the results of the comparison, to the person requesting the diagnostic test via the Internet (¶38; ln.11-15) with reporting-consulting subsystem 22 further transmitting remarkable results bearing an abnormal results flag to an embedded consultant (¶38; ln.8-11), with reporting-consulting subsystem 22 providing at least one template for selection by a consultant to generate a consultative report based upon the test results. (¶38; ln.15-17). and with the template including at least one Internet link to an additional source of diagnostic information (¶48; ln.1-4).

VI. Grounds of Rejection to be Reviewed on Appeal

1. The rejection of Claims 1-21 under 35 U.S.C. 101, as being directed to non-statutory subject matter.

2. The rejection of Claims 18 and 22-28, under 35 U.S.C. 112, second paragraph, as being indefinite.

3. The rejection of Claims 1, 3, 9, 11, 13, 14, and 15 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1).

4. The rejection of Claims 2, 4, 5, 12, 22, 26, and 27 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and further in view of Edelson et al. (US 5,737,539 A).

5. The rejection of Claim 28 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and Edelson et al. (US 5,737,539 A), and further in view of Ross et al. (US 5,823,948 A).

6. The rejection of Claims 6, 7, and 8 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and further in view of Dworkin (US PGPUB 2002/0071540 A1).

7. The rejection of Claim 10 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and further in view of Matsuoka et al. (US 5,819, 242 A).

8. The rejection of Claims 16 and 18 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and further in view of Smith (US PGPUB 2003/0069759 A1).

9. The rejection of Claim 17 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1) and Smith (US PGPUB 2003/0069759 A1), and further in view of Edelson et al. (US 5,737,539 A).

10. The rejection of Claims 19 and 20 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1) and Smith (US PGPUB 2003/0069759 A1), and further in view of Dworkin (US PGPUB 2002/0071540 A1).

11. The rejection of Claim 21 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1) and Smith (US PGPUB 2003/0069759 A1), and further in view of Ross et al. (US 5,823,948 A).

12. The rejection of Claims 23, 24, and 25 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1) and Edelson et al. (US 5,737,539 A), and further in view of Smith (US PGPUB 2003/0069759 A1).

VII. Arguments

The rejection of Claims 1-21 under 35 U.S.C. 101, as being directed to non-statutory subject matter.

1. Claims 1 – 21 stand rejected under 35 U.S.C. 101 on the grounds that the claimed invention is directed to non-statutory subject matter. Specifically, Claims 1, 14, and 16 recite an "embedded consultant" (i.e., a human being). The Examiner states that

> "where a claim is directed to apparatus "attached to" the human body or any part thereof it may be appropriate to make a rejection under 35 U.S.C. 101 with an explanation that, because the claim positively recites a part of the human body, it is directed to non-statutory subject matter."

Appellants strenuously object to the characterization of their claims as having an apparatus "attached to" a human body. Rather, in the context of this application, the 'human body' is a consultant who is associated with the claimed reporting-consulting subsystem. Surely the Examiner understands that no part of the claimed invention is physically attached to the body of a physician who is charged with the responsibility of providing consultations to those requesting services through the claimed system. Paragraph 8 of Appellants' specification provides a lucid, explicit definition for the term 'embedded'. It is quite clear that consultants are associates of the laboratory and an integral component of the testing the reporting process, and wholly dedicated to the provision of laboratory testing services and serve as professionals meeting the needs of test ordering clinicians. Clearly, use of the term 'embedded' does not mean that laboratory apparatus is 'attached' to the consultants' bodies.

Appellants respectfully submit that the Examiner's rejection under 35 U.S.C. 101 is wholly without merit and, as a result, each of Claims 1 – 21 are allowable over the rejection.

The rejection of Claims 18 and 22-28, under 35 U.S.C. 112, second paragraph, as being indefinite.

2. Claims 18 and 22 – 28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of use of the term "desirable" in Claim 18 and "remarkable" in Claim 22. The Examiner states that the specification does not provide a standard for ascertaining the definition of these terms and that one of ordinary skill in the art would accordingly not be reasonably apprised of the scope of the invention.

Appellants submit that the meaning of the terms 'desirable' and 'remarkable', in the context of the claimed system which is used to obtain and process laboratory results, is crystal clear, especially when teamed with the usage in Appellants' specification. Appellants respectfully direct the Board's attention to Appellants' specification at Paragraph 43, wherein usage of the term "remarkable", is defined as abnormal test results, as gauged by a comparison of test results with predetermined reference ranges. The term 'desirable', is used in several claims in conjunction with reflexive testing, and the meaning is clear from the claims, particularly in the context of Appellants' specification at Paragraph 15, wherein desirability is defined inherently by using positive results obtained during a previous round of testing and previously drawn blood samples to accomplish reflexive testing. Because the meaning of the terms 'desirable' and 'remarkable' is clear from the context of Appellants' specification, each of Claims 18 and 22 – 28 is allowable over the Examiner's rejection.

The rejection of Claims 1, 3, 9, 11, 13, 14, and 15 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1).

3. The Examiner states that Atlas Lab Works shows an order entry subsystem for submitting orders; a laboratory for receiving orders and managing patients; filling the orders and generating test results; a data storage subsystem for test results; a triage subsystem for comparing test results downloaded from data storage subsystem; the triage subsystem setting an abnormal results flag in the event that the test results are outside a reference range; a reporting-consulting subsystem for receiving results in comparison from the triage subsystem; the reporting-consulting subsystem transmitting processed test results to the person requesting at least one test; and the reporting-consulting subsystem transmitting results bearing an abnormal results flag to an embedded consultant. Notwithstanding the previous recitation of what the Examiner found with the four corners of Atlas LabWorks, the Examiner admits that Atlas LabWorks does not disclose a consultant or a reporting-consulting subsystem providing at least one template for a suggestion by a consultant to generate a consultative report concerning the test results. For this content, the Examiner looks to Bladen. The Examiner states that Bladen discloses a risk assessment system including consultant-selected templates. The Examiner concludes with the argument that it would have been obvious to one of ordinary skill in the art at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks so as to have included consultant-selected templates, in accordance with the teaching of Bladen, in order to allow for the effective reporting of the consultants findings for laboratory results, and to do so readily and easily by a person of ordinary skill in the art with neither undue experimentation, nor risk of unexpected results.

Appellants have reviewed the Atlas LabWorks web-site information relied upon by the Examiner, and note that the Examiner is correct in his statement that Atlas LabWorks does not disclose either a consultant, or a reporting consulting subsystem. Moreover, Bladen does not disclose either of these elements, either. Bladen discloses a method and system for assessing compliance with standards and for minimizing risks associated with noncompliance with standards of care. Although it is true that the term 'template' is used in Bladen's specification, Appellants respectfully submit that a simple keyword search of Bladen would show use of the word 'template' without any indication that the template has anything to do with the case being considered here. Bladen's template files are intended to accommodate different risk modalities, such as food, and other health and safety questions and to generate assessment manuals. There is nothing in Bladen, or for that matter in Atlas LabWorks, to either teach or suggest, whether separately, or in combination with each other, the use of a human consultant working with a template provided by a reporting-consulting subsystem to produce a consultative report concerning test results obtained from a patient. The fact of the matter is that neither Atlas LabWorks, nor Bladen, nor any combination of the two, either teaches or suggests the generation of a consultative report by a human consultant, working with a template selected by the consultant providing the consultative report. The system in Claim 1 is therefore allowable over the Examiner's rejection.

Claims 3, 9, 11 and 13 stand rejected over Atlas LabWorks and Bladen as applied to Claim 1, and further, according to the Examiner, Atlas LabWorks disclosure including a template provided by a reporting-consulting subsystem, with a reference range being determined as a function of at least one prior recorded test result, and an alert subsystem for establishing a time-based test sequence in the event that patient test results are not entered into a data storage

subsystem according to the specified time interval. Also, interpretive data include at least one of patient-specific archival data, generic tabular data, generic graphical data, and patient-specific graphical data.

Appellants respectfully submit that neither Atlas LabWorks, nor Bladen, whether taken singularly, or in combination with each other, either teach or suggest a template having a data source providing data for generating a consultative report. Moreover, there is nothing in Atlas LabWorks and Bladen about reference ranges determined as a function of a prior-recorded test result, an alert subsystem for establishing a time-based test sequence, or interpretive data comprising at least one of the patient's specific data, etc. As a result, each of Claims 3, 9, 11 and 13 are clearly allowable over the Examiner's rejection.

Claims 14 and 15 stand rejected over Atlas LabWorks, with the Examiner reciting an internet-based order entry subsystem, a data storage subsystem, a triage subsystem, and other element.. The Examiner admits that Atlas LabWorks does not include providing a template selectable by an embedded consulting physician, and with the consulting physician generating a consultative report.

As noted above, Appellants respectfully submit that neither Atlas LabWorks, nor Bladen either teach or suggest a triage subsystem, in a reporting-consulting subsystem, especially a subsystem providing a template selectable by an embedded consulting physician, and with the physician generating a consultative report using the template with a network terminal, with the report being based upon the test results and with the template including at least one data source for providing data for generating a report. None of these features is found within the four corners of either Atlas LabWorks, or Bladen, nor are they taught, suggested, urged, or disclosed

by either of the cited references, or their combination. As a result, Claims 14 and 15 are clearly allowable over the Examiner's rejection.

The rejection of Claims 2, 4, 5, 12, 22, 26, and 27 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and further in view of Edelson et al. (US 5,737,539 A).

4. The Examiner admits that Atlas LabWorks and Bladen do not disclose a data source for providing interpretive data; a computer-linked source of additional information for use by an embedded consultant for generating a consultative report; a computer-linked source of additional information which is internet-based; and a template incorporating interpretive data for use by the embedded consultant in the event that test results require additional analysis. The Examiner states that Edelson discloses a prescription creation system which includes providing interpretive data over the internet. The Examiner argues that it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the laboratory test management system of Atlas LabWorks/Bladen to provide a source to have included the provision of interpretative data over the internet in accordance with the teaching of Edelson, with the argument that so doing could be performed readily and easily by any person of ordinary skill in the art with neither undue experimentation, nor risk of unexpected results.

Appellants respectfully submit that the Examiner's addition of Edelson to the combination of Atlas LabWorks and Bladen is to no avail because Edelson teaches nothing more than a system for providing prescription information to doctors to allow them to specify a correct drug for a patient. Edelson, whether taken singularly, or in a combination with either Atlas LabWorks or Bladen, or both, neither teaches nor suggests anything regarding the examination

of patient data with an eye to generation of a consultative report by means of an embedded consultant. As a result, Claims 2, 4, 5 and 12 are allowable over the Examiner's rejection and should be passed to issue.

Claim 22 stands rejected over Atlas LabWorks, Bladen, and Edelson on the asserted grounds that Edelson provides an internet link with diagnostic information. Although Edelson does contemplate use of the internet to provide information, as noted above, neither Atlas LabWorks, nor Bladen, nor Edelson either teaches or suggests anything regarding the use of a template specified by an embedded consultant providing a consultative report. As a result, Claim 22 should be passed to issue over the Examiner's rejection.

Claims 26 and 27 stand rejected over Atlas LabWorks, Bladen, and Edelson. Claims 26 and 27 depend from Claim 22, which recites the previously described triage subsystem and embedded consultant, and which is allowable for the reasons cited. As a result, Claims 26 and 27 are allowable over the Examiner's rejection and should be passed to issue.

The rejection of Claim 28 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and Edelson et al. (US 5,737,539 A), and further in view of Ross et al. (US 5,823,948 A).

5. The Examiner utilizes Ross for its recitation of data organization in a format that facilitates CPT coding. Appellants respectfully submit that Claim 28 is allowable over the rejection because neither Atlas LabWorks nor Bladen nor Edelson nor Ross either teaches or suggests a billing routine, as applied within the context of Appellants' system for providing clinical laboratory services, including an invoice bearing an AMA CPT code. Although Ross

discusses CPT coding, there is nothing in Ross to teach or suggest that an invoice is provided with such a code. Moreover, Claim 28 depends from Claim 22 which is allowable for the previously described reasons, and Claim 28 should therefore be passed to issue over the Examiner's rejection.

The rejection of Claims 6, 7, and 8 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and further in view of Dworkin (US PGPUB 2002/0071540 A1).

6. The Examiner incorporates Dworkin for a conferencing subsystem for scheduling a conference between a test requester and the embedded consultant, including a computer net meeting and the scheduling of the net meeting. Appellants note that although Dworkin teaches a conferencing system, Dworkin provides none of the detail missing from the earlier rejections based upon Atlas, Bladen, and Edelson, and as a result, Claims 6, 7 and 8, all which depend from Claim 1, are allowable and should be passed to issue.

The rejection of Claim 10 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and further in view of Matsuoka et al. (US 5,819, 242 A).

7. The Examiner utilizes Matsuoka for its teaching of uploading previous test results for a number of patients, and a subroutine for predicting future test results based at least in part upon the stored test results. Appellants respectfully submit that Matsouka discloses a fuzzy logic network, and nothing regarding the invention set forth in Claim 1, from which Claim 10 depends, and as a result Claim 10 is allowable.

The rejection of Claims 16 and 18 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1), and further in view of Smith (US PGPUB 2003/0069759 A1).

8. The Examiner incorporates Smith for its teaching of communicating laboratory test results and the like over the Internet. Smith, however, whether taken singularly, or in combination with Atlas LabWorks and Bladen, neither teaches nor suggests Appellants' claimed invention as set forth in Claims 16, because as noted above, neither Atlas LabWorks nor Bladen, nor for that matter, Smith, either teaches or suggests, urges or discloses using a network to cause laboratory test results to be transmitted directly to the test requester in the event test results are within a reference range, while causing the test results to be transmitted by a networked terminal device to a consulting physician via a consultative reporting-consulting subsystem in the event that the test results are outside the reference range, while using results lying outside of the reference range in the reporting-consulting subsystem to provide at least one selectable report template, and using the report template and a consulting physician to generate a consultative report, which is communicated with an electronic signature to the test requester. None of this is found within Atlas LabWorks or Bladen, or Smith, or any teaching or suggestion or urging or disclosure of any of these references, and as a result, Claim 16 is allowable over the Examiner's rejection.

Claim 18 stands rejected on the same basis of Claim 16, with the Examiner's additional assertion that Atlas LabWorks discloses requesting reflexive tests. Appellants respectfully submit however, that there is nothing in the Atlas LabWorks disclosure which indicates anything regarding reflexive testing, and as a result, Claim 18 is allowable over the Examiner's rejection.

The rejection of Claim 17 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1) and Smith (US PGPUB 2003/0069759 A1), and further in view of Edelson et al. (US 5,737,539 A).

9. Claim 17 stands rejected on the same basis as Claim 16, namely over the combination of Atlas/Bladen/Smith, with the addition of Edelson for an importable additional data source providing test result driven data for generating a consultative report. Edelson, however, describes nothing regarding the claimed consultative reporting, and as a result, the combination of Atlas/Bladen/Smith and Edelson, whether taken singularly, or in combination of each other, cannot comprise a colorable basis for rejection of Claim 17, and this claim, too, should be passed to issue over the Examiner's rejection.

The rejection of Claims 19 and 20 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1) and Smith (US PGPUB 2003/0069759 A1), and further in view of Dworkin (US PGPUB 2002/0071540 A1).

10. Again, Dworkin is cited for its disclosure of a conferencing system. However, because Dworkin teaches nothing regarding the basics of the claimed system detailed in independent Claim 16, Claims 19 and 20 are allowable over the Examiner's rejection and should be passed to issue.

The rejection of Claim 21 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1) and Smith (US PGPUB 2003/0069759 A1), and further in view of Ross et al. (US 5,823,948 A).

11. Ross is cited for its disclosure of billing of the patient's insurer for time expended by the physician to analyze the test results to draft a consultative report. However, Ross discloses nothing regarding any specific billing process, and Claim 21 is therefore allowable over the Examiner's rejection.

The rejection of Claims 23, 24, and 25 under 35 U.S.C. §103(a) as being unpatentable over Atlas Medical, Inc. Atlas LabWorks web site dated 2 August, 2002, in view of Bladen et al. (US PGPUB 2002/0099586A1) and Edelson et al. (US 5,737,539 A), and further in view of Smith (US PGPUB 2003/0069759 A1).

12. The Examiner uses Smith for its teaching of a consultant's electronic signature, and for a digital signature. However, as noted above, Smith is devoid of any teaching of an embedded consultant system employing templates to produce a consultative report which is provided to a primary care physician, and as a result, Claims 23, 24 and 25, all of which depend either directed or indirectly from independent Claim 22, are clearly allowable over the Examiner's rejection.

VIII. Conclusion

For the foregoing reasons, Appellants respectfully request that the Board direct the Examiner in charge of this examination to withdraw the rejections and to issue each of the claims remaining in this case.

Respectfully submitted,

Date: 2/5/10

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IX. Claims Appendix

1. A system for providing clinical laboratory test ordering and results reporting with an embedded consultation service, comprising:

an order entry subsystem for submitting orders for at least one diagnostic test;

a laboratory for receiving said orders and for managing patients to fill said orders, thereby generating test results;

a data storage subsystem for receiving and retaining test results from said laboratory;

a triage subsystem for comparing test results downloaded from said data storage subsystem with a predetermined reference range specific to such results, with said triage subsystem setting an abnormal results flag in the event that the test results are outside of said reference range; and

a reporting-consulting subsystem for receiving the results of said comparison from said triage subsystem, with said reporting-consulting subsystem transmitting the processed test results, comprising at least the results of said comparison, to the person requesting said at least one diagnostic test, and with the reporting-consulting subsystem further transmitting results bearing an abnormal results flag to an embedded consultant, with said reporting-consulting subsystem providing at least one template for selection by said consultant to generate a consultative report concerning the test results.

2. A system according to Claim 1, wherein said template provided by said reporting-consulting subsystem further comprises at least one data source for providing interpretive data for generating said consultative report.

3. A system according to Claim 1, wherein said template provided by said reporting-consulting subsystem further comprises at least one data source for providing data for generating

said consultative report, with said data source providing said data as a function of at least the value of said test results.

4. A system according to Claim 1, wherein said template provided by said reporting-consulting subsystem further comprises at least one computer-linked source of additional information for use by said consultant for generating said consultative report.

5. A system according to Claim 4, wherein said computer-linked source of additional information comprises an Internet-based source.

6. A system according to Claim 1, wherein said reporting-consulting subsystem further comprises a conferencing subsystem for scheduling a conference between the person submitting the test request and the embedded consultant who generated said consultative report.

7. A system according to Claim 1, wherein said reporting-consulting subsystem further comprises a conferencing subsystem for scheduling a computer net meeting between the test requester and the embedded consultant who generated said consultative report.

8. A system according to Claim 1, wherein said reporting-consulting subsystem further comprises a conferencing subsystem for scheduling a net meeting between the test requestor, the embedded consultant who generated said consultative report, and at least one additional consultant.

9. A system according to Claim 1, wherein said reference range is determined as a function of at least one prior recorded test result for the patient being tested.

10. A system according to Claim 1, wherein said reporting-consulting subsystem further comprises a routine for selectively uploading previous test results for a plurality of patients and a subroutine for predicting future test results based at least in part upon said stored test results.

11. A system according to Claim 1, wherein said reporting-consulting subsystem further comprises an alert subsystem for establishing a time-based test sequence,with said reporting-consulting subsystem contacting said clinician in the event that patient test results are not entered into said data storage subsystem according to a specified time interval, with said alert subsystem also having the capability of causing the clinician to be contacted in the event that said test results indicate that said patient requires immediate intervention.

12. A system according to Claim 1, wherein said template incorporates interpretative data for use by the embedded consultant in the event that the test results require additional analysis.

13. A system according to Claim 12, wherein said interpretative data comprise at least one of: patient-specific archival data, generic tabular data, generic graphical data, and patient-specific graphical data.

14. A system for facilitating the provision of clinical laboratory services, comprising:

an Internet based order entry subsystem, accessible by clinicians, for submitting orders for diagnostic tests to a laboratory;

a data storage subsystem for receiving and retaining both contemporary and archival laboratory test results;

a triage subsystem for downloading said test results from said data storage subsystem, with said triage subsystem comparing said test results with predetermined reference range values, with said triage subsystem causing the test results to be transmitted over a computer network to both the requesting clinician and to a reporting-consulting subsystem in the event that the test results are outside said reference range values; and

a reporting-consulting subsystem for receiving said test results lying outside of

said reference range, with said reporting-consulting subsystem providing at least one template, selectable by an embedded consulting physician using a networked terminal, with said consulting physician generating a consultative report using said template and said networked terminal, and with said report being based upon said test results, and with said template comprising at least one data source for providing data for generating said report, with said data source providing said data as a function of at least the value of said test results.

15. A system according to Claim 14, wherein said triage subsystem causes archival test results contained within said data storage subsystem to be transferred to said clinician at the same time contemporary test results are transferred to the clinician.

16. A method for providing clinical laboratory services, comprising the steps of:

submitting an order to a laboratory for a diagnostic test by means of a networked terminal device;

managing a patient to fill said test order, thereby generating test results;

loading said test results into a data storage subsystem;

comparing said test results contained within said data storage subsystem with predetermined reference range values, and thereafter causing the test results to be transmitted directly to the test requestor, using a networked terminal device, in the event that the test results are within said reference range, but causing the test results to be transmitted by a networked terminal device to a consulting physician via a consultative reporting-consulting subsystem in the event that the test results are outside said reference range;

receiving said test results lying outside of said reference range in a reporting-consulting subsystem, and using said reporting-consulting subsystem to provide at least one selectable report template;

using said report template and said consulting physician to generate a consultative report based at least in part upon the test results; and

communicating said consultative report, bearing an electronic signature, to the test requester by means of a networked terminal device.

17. A method according to Claim 16, wherein said report template incorporates at least one importable additional data source for providing test result driven data for generating said consultative report.

18. A method according to Claim 16, further comprising the steps of requesting and performing additional reflexive tests in the event that said test results indicate that such testing is desirable, with the results of said reflexive tests being communicated to said test requester by means of a networked terminal device.

19. A method according to Claim 16, further comprising the step of linking the test requestor to a conferencing system by means of a networked terminal device, for scheduling a conference with the consultant who generated said consultative report.

20. A method according to Claim 16, further comprising the step of linking the test requestor to a conferencing system by means of a networked terminal device, for scheduling a net meeting with at least the consultant who generated said consultative report.

21. A method according to Claim 16, further comprising the step of billing the patient's insurer for the time expended by the consulting physician to analyze said test results and to draft said consultative report.

22. A system for providing clinical laboratory services, comprising:

an Internet based order entry subsystem for use by a clinician to submit orders for diagnostic tests;

a data storage subsystem for receiving and retaining test results from a clinical laboratory;

a triage subsystem for comparing said test results with predetermined range values, with said triage subsystem causing the test results to be transmitted by a reporting-consulting subsystem directly to the test requestor via the Internet, and with said triage subsystem causing the test results to be transmitted to a reporting-consulting subsystem in the event that the test results are remarkable in view of said predetermined range values, with said reporting-consulting subsystem receiving said remarkable test results and providing at least one template for selection by a consultant to generate a consultative report concerning the test results, and with said template comprising at least one Internet link to an additional source of diagnostic information.

23. A system according to Claim 22, wherein said reporting-consulting subsystem provides for the affixing of said consultant's electronic signature to said consultative report and for sending the consultative report to the requesting clinician via the Internet.

24. A system according to Claim 23, wherein said electronic signature is a digital signature.

25. A system according to Claim 23, wherein said electronic signature is a digital signature meeting the requirements of the Health Insurance Portability and Accountability Act ("HIPAA").

26. A system according to Claim 22, wherein said predetermined range values comprise a reference range selected as a function of at least one prior test result of the patient being tested.

27. A system according to Claim 22, wherein said consultative report comprises at least one URL for use by the clinician receiving the consultative report.

28. A system according to Claim 22, further comprising a billing routine for invoicing said patient's insurer by means of an invoice bearing an AMA CPT code.

X. Evidence Appendix

None.

XI. Related Proceedings Appendix

None.